UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,723	02/20/2004	Yuniko Shibata	249169US0	4185

22850 7590 11/01/2005

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,723	SHIBATA, YUNIKO	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 08/05/05.

The amendment filed 08/05/05 affects the application, 09/943,650 as follows:

1. Claims 3-6 have been amended. Claims 1 and 2 have been canceled. New Claims 7-10 have been added. This leaves claims 3-10. Upon further consideration the examiner has determined that claim 6 is not free of the prior art as stated in the prior Office Action. Consequently, this office action is made Non-final.

The responsive to applicants' arguments is contained herein below.

Claims 3-10 are pending in application

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 5, 6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Balazs et al. (Radiation Research (1959), vol.11, pages 149-64).

In claim 6, applicant claims "A method for producing a purified low molecular weight glycosaminoglycan, having a molecular weight of 200 to 1,000,00 Da, which comprises irradiating a glycosaminoglycan containing contaminants with an ultraviolet ray to lower the molecular weight of the glycosaminoglycan and simultaneously decompose and remove the contaminants. Balazs et al. disclose applicant's method of producing a low molecular weight glycosaminoglycan (hyaluronic acid), which comprises irradiating the glycosaminoglycan

(hyaluronic acid) with an ultraviolet ray (ultraviolet light) to lower the molecular weight of the glycosaminoglycan and simultaneously decompose and remove the contaminants (see abstract). The examiner considers the hyaluronic acid produced to be low molecular weight hyaluronic acid of same claimed Da units, since Balazs et al. disclose that the glycoaminoglycan (hyaluronic acid) (same as applicant's) decreased in mol. weight and length upon irradiation with an ultraviolet ray (ultraviolet light) of the same wave length (2670 Å (267 nm)) (see abstract). The examiner considers Balazs et al.'s method one which also comprises the simultaneous decomposition and removal the contaminants, since Balazs et al. produces low molecular weight glycosaminoglycan by irradiating the same glycosaminoglycan (hyaluronic acid) as applicant with the same ultraviolet ray (ultraviolet light) of same wavelength. It should be noted that applicant's claimed decomposition and removal of the contaminants occurs simultaneously with the as the low molecular weight glycosaminoglycan is produced by irradiation. Claim 3, which is drawn to the method according to claim 6, wherein the glycosaminoglycan is selected from the group consisting of hyaluronic acid, chondroitin, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate and keratin sulfate, is anticipated by Balazs et al., since Balazs et al. use the glycosaminoglycan, hyaluronic acid (see abstract). Claim 5, which is drawn to a method of claim 6, wherein the ultraviolet ray to be irradiated has a wavelength of 250 to 450 nm, is anticipated by Balazs et al., since Balazs et al.'s hyaluronic acid product is formed with a maximum wave length at 2670 Å (267 nm) (see abstract). Claims 9 and 10 which are drawn to the method according to claim 6 wherein the low molecular weight is of specific molecular weight is also anticipated by Balazs et al. (see abstract). The examiner considers the hyaluronic acid produced to be low molecular weight hyaluronic acid of same claimed Da units, since

Balazs et al. disclose that the glycoaminoglycan (hyaluronic acid) (same as applicant's) decreased in mol. weight and length upon irradiation with an ultraviolet ray (ultraviolet light) of the same wave length (2670 Å (267 nm)) (see abstract). The examiner considers Balazs et al.'s method one which also comprises the simultaneous decomposition and removal the contaminants, since Balazs et al. produces low molecular weight glycosaminoglycan by irradiating the same glycosaminoglycan (hyaluronic acid) as applicant with the same ultraviolet ray (ultraviolet light) of same wavelength. It should be noted that applicant's claimed decomposition and removal of the contaminants occurs simultaneously with the as the low molecular weight glycosaminoglycan is produced by irradiation.

Claims 3, 5, 6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hvidberg et al. (Acta Pharmacologica et Toxicologica (1959), 15, 356-64).

In claim 6, applicant claims "A method for producing a purified low molecular weight glycosaminoglycan, having a molecular weight of 200 to 1,000,00 Da, which comprises irradiating a glycosaminoglycan containing contaminants with an ultraviolet ray to lower the molecular weight of the glycosaminoglycan and simultaneously decompose and remove the contaminants.

Hvidberg et al. disclose applicant's method of producing a low molecular weight glycosaminoglycan (hyaluronic acid), which comprises irradiating the glycosaminoglycan (hyaluronic acid) with an ultraviolet ray (ultraviolet light) to lower the molecular weight of the glycosaminoglycan and simultaneously decompose and remove the contaminants (see abstract). Hvidberg et al. disclose that the molecular weight hyaluronic acid products were about 1000 (see abstract). The examiner considers Hvidberg et al.'s method one which also comprises the

simultaneous decomposition and removal the contaminants, since Hvidberg et al. produces low molecular weight glycosaminoglycan of same low molecular weight (about 1000) by irradiating the same glycosaminoglycan (hyaluronic acid) as applicant with the same ultraviolet ray (ultraviolet light) of same wavelength. It should be noted that applicant's claimed decomposition and removal of the contaminants occurs simultaneously with the as the low molecular weight glycosaminoglycan is produced by irradiation. Claim 3, which is drawn to the method according to claim 6, wherein the glycosaminoglycan is selected from the group consisting of hyaluronic acid, chondroitin, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate and keratin sulfate, is anticipated by Hvidberg et al., since Hvidberg et al. use the glycosaminoglycan, hyaluronic acid (see abstract). Claim 5, which is drawn to a method of claim 6, wherein the ultraviolet ray to be irradiated has a wavelength of 250 to 450 nm, is anticipated by Hvidberg et al., since Hvidberg et al.'s hyaluronic acid product use light of wave length at 2550 Å (255 nm) (see abstract).

Claims 3, 5-7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Khan et al. (Polymer Photochemistry (1981), 1(1), 33-41).

In claim 6, applicant claims "A method for producing a purified low molecular weight glycosaminoglycan, having a molecular weight of 200 to 1,000,00 Da, which comprises irradiating a glycosaminoglycan containing contaminants with an ultraviolet ray to lower the molecular weight of the glycosaminoglycan and simultaneously decompose and remove the contaminants. Khan et al. disclose applicant's method of producing a low molecular weight glycosaminoglycan (chondroitin 4-sulfate or chondroitin sulfate A), which comprises irradiating the glycosaminoglycan (chondroitin sulfate A) with an ultraviolet ray (ultraviolet light) to lower

the molecular weight of the glycosaminoglycan and simultaneously decompose and remove the contaminants (see abstract). The examiner considers the chondroitin sulfate A produced to be low molecular weight hyaluronic acid of same claimed Da units, since Khan et al. disclose that the glycoaminoglycan (chondroitin sulfate A) (same as applicant's) was degraded (decreased in mol. weight and length) upon irradiation with an ultraviolet ray (ultraviolet light) of the same wave length (253.7 nm)) (see abstract). The examiner considers Khan et al.'s method one which also comprises the simultaneous decomposition and removal the contaminants, since Khan et al. produces low molecular weight glycosaminoglycan by irradiating the same glycosaminoglycan (chondroitin sulfate A) as applicant with the same ultraviolet ray (ultraviolet light) of same wavelength. It should be noted that applicant's claimed decomposition and removal of the contaminants occurs simultaneously with the as the low molecular weight glycosaminoglycan is produced by irradiation. Claim 3, which is drawn to the method according to claim 6, wherein the glycosaminoglycan is selected from the group consisting of hyaluronic acid, chondroitin, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate and keratin sulfate, is anticipated by Khan et al., since Khan et al. use the glycosaminoglycan, chondroitin sulfate A (see abstract). Claim 5, which is drawn to a method of claim 6, wherein the ultraviolet ray to be irradiated has a wavelength of 250 to 450 nm, is anticipated by Khan et al., since Khanet al.'s chondroitin sulfate A product is formed with a maximum wave length at 253.7 nm (see abstract). Claims 9 and 10 which are drawn to the method according to claim 6 wherein the low molecular weight is of specific molecular weight is also anticipated by Khan et al. (see abstract). The examiner considers the chondroitin sulfate A produced to be low molecular weight hyaluronic acid of same claimed Da units, since Khan et al. disclose that the glycoaminoglycan (chondroitin sulfate A)

(same as applicant's) decreased in mol. weight and length upon irradiation with an ultraviolet ray (ultraviolet light) of the same wave length 253.7 nm (see abstract). The examiner considers Khan et al.'s method one which also comprises the simultaneous decomposition and removal the contaminants, since Khan et al. produces low molecular weight glycosaminoglycan by irradiating the same glycosaminoglycan (chondroitin sulfate A) as applicant with the same ultraviolet ray (ultraviolet light) of same wavelength. It should be noted that applicant's claimed decomposition and removal of the contaminants occurs simultaneously with the as the low molecular weight glycosaminoglycan is produced by irradiation. Claim 7, which is drawn to the method according to claim 3, wherein the glycosaminoglycan is selected from the group consisting of chondroitin sulfate A, chondroitin sulfate C, chondroitin sulfate D and chondroitin sulfate E, is anticipated by Khan et al., since Khan et al. use the glycosaminoglycan, chondroitin sulfate A (see abstract).

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Balazs et al. (Radiation Research (1959), vol.11, pages 149-64).

In claim 4 and 8, applicant claims "The method according to claim 6, wherein temperature is maintained at 1 to 37°C during ultraviolet ray irradiation. Claim 8 is drawn to a method of claim 4, wherein temperature is maintained at 10 to 25°C during ultraviolet ray irradiation.

Balazs et al. disclose applicant's method of producing a low molecular weight glycosaminoglycan (hyaluronic acid), which comprises irradiating the glycosaminoglycan (hyaluronic acid) with an ultraviolet ray (ultraviolet light) to lower the molecular weight of the glycosaminoglycan and simultaneously decompose and remove the contaminants (see abstract). The examiner considers the hyaluronic acid produced to be low molecular weight hyaluronic acid of same claimed Da units, since Balazs et al. disclose that the glycoaminoglycan (hyaluronic acid) (same as applicant's) decreased in mol. weight and length upon irradiation with an ultraviolet ray (ultraviolet light) of the same wave length (2670 Å (267 nm)) (see abstract). The examiner considers Balazs et al.'s method one which also comprises the simultaneous decomposition and removal the contaminants, since Balazs et al. produces low molecular weight glycosaminoglycan by irradiating the same glycosaminoglycan (hyaluronic acid) as applicant with the same ultraviolet ray (ultraviolet light) of same wavelength. It should be noted that applicant's claimed decomposition and removal of the contaminants occurs simultaneously with the as the low molecular weight glycosaminoglycan is produced by irradiation. Although Balazs et al. is silent about the temperature during the ultraviolet irradiation this does not mean that the

temperature is not between 10-25°C and 1-37°C. Balazs et al. anticipate the claims if their the temperature is 10-25°C and 1-37°C. Balazs et al. render the claims as being obvious if their temperature is substantially close to the claimed limitation of 10-25°C and 1-37°C. In fact, one may deduce that Balaz et al. temperature would be about room temperature (approx. 25 °C), since such ultraviolet irradiation of samples are normally performed at room temperature.

Claims 4 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hvidberg et al. (Acta Pharmacologica et Toxicologica (1959), 15, 356-64).

In claim 4 and 8, applicant claims "The method according to claim 6, wherein temperature is maintained at 1 to 37°C during ultraviolet ray irradiation. Claim 8 is drawn to a method of claim 4, wherein temperature is maintained at 10 to 25°C during ultraviolet ray irradiation.

Hvidberg et al. disclose applicant's method of producing a low molecular weight glycosaminoglycan (hyaluronic acid), which comprises irradiating the glycosaminoglycan (hyaluronic acid) with an ultraviolet ray (ultraviolet light) to lower the molecular weight of the glycosaminoglycan and simultaneously decompose and remove the contaminants (see abstract). Hvidberg et al. disclose that the molecular weight hyaluronic acid products were about 1000 (see abstract). The examiner considers Hvidberg et al.'s method one which also comprises the simultaneous decomposition and removal the contaminants, since Hvidberg et al. produces low molecular weight glycosaminoglycan of same low molecular weight (about 1000) by irradiating the same glycosaminoglycan (hyaluronic acid) as applicant with the same ultraviolet ray (ultraviolet light) of same wavelength. It should be noted that applicant's claimed decomposition

and removal of the contaminants occurs simultaneously with the as the low molecular weight glycosaminoglycan is produced by irradiation. Although Hvidberg et al. is silent about the temperature during the ultraviolet irradiation this does not mean that the temperature is not between 10-25°C and 1-37°C. Hvidberg et al. anticipate the claims if their the temperature is 10-25°C and 1-37°C. Hvidberg et al. render the claims as being obvious if their temperature is substantially close to the claimed limitation of 10-25°C and 1-37°C. In fact, one may deduce that Hvidberg et al. temperature would be about room temperature (approx. 25 °C), since such ultraviolet irradiation of samples are normally performed at room temperature. It should be noted that applicant has not claimed or recited any steps in their process that even fairly suggests that their process would produce a different low molecular glycoaminoglycan product to those of the process of the foregoing prior art documents.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

October 28, 2005.

SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1200

SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1200